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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/566,976

08/09/2006

Fredrik Joabsson

613-102

2888

23117

7590

09/25/2009

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EXAMINER

YOUNG, MICAH PAUL

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

09/25/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/566,976	Applicant(s) JOABSSON ET AL.	
	Examiner MICAH-PAUL YOUNG	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/2/06</u> . | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 2/2/06 was filed in a timely manner. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 recites the amphiphillic particles comprise at least 130% of the maximum incorporation of equivalent particle not comprising any active agent. First how equivalent are the particles if they do not have any active agent? Second if the instant particles that comprise an active agent at least 130% of equivalent particles with no active agent (zero active agent), that would mean the instant particles have zero active agent as well (130% of 0 = 0). How can the instant particle recite an incorporated active agent, yet have zero percent of an active agent?

Claims 11-20 depend from claim 10, which is held as indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-5, 8, 10-14, 16-20 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Ribier et al (USPN 6,066,328 hereafter '328).

The '328 patent teaches a amphiphillic composition comprising an active agent and a method of making said formulation (abstract). The formulation is a colloidal milk, cream or gel form (col. 6, lin. 16-18). The formulation comprises an amphiphillic lipid, active agent, and surfactant with HLB up to 12 (col. 3, lin. 30-35, col. 4, lin. 29-50). The components are mixed forming a dispersion of the active agent, followed by heating the mixture to a temperature from 20-95 °C from 10-60 minutes (col. 6, lin. 30-35). The mixture is cooled to around room temperature (col. 7, lin. 1-25). The formulation comprises multiple amphiphillic compounds including oils, and surfactants (Examples). The formulation can comprise fragrances, perfumes and water as a carrier (col. 4, lin. 41, examples). Regarding the stability of the particles, it is the position of the Examiner that such limitations are functional and dependent from the compositional components of the particles. Since a composition and its properties cannot be separated, the same components must have the same properties. As such the prior art discloses amphiphillic particles comprising the same amphiphillic polymers and incorporated active agents, therefor their stability must also be the same.

Regarding claim 10, it is the position of the Examiner that the claim limitations reciting the incubation time and temperature are merely product by process limitation and do not overcome the prior art. The claim recites particles comprising an active agent incorporated into a particle comprising amphiphillic polymers. Even though product-by-process claims are limited

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by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

For these reasons the claims are anticipated.

Claims 1-3, 6, 7, and 9-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Landh et al (USPN 5,531,925 hereafter ‘925).

The ‘925 patent teaches a method of making amphiphillic particles comprising forming a dispersion of particles comprising active agents and amphiphillic polymers at an elevated temperature and cooling the resultant mixture (claim 7-11). The particles are equilibrated at a temperature (37°C) followed by freeze-drying (col. 11, lin. 1-26). The particles are colloidal (claims 16 and 17). The core of the particles is completely non-lamellar (claim 1). The particles further comprise fragmented compounds including, fatty alcohols, and block copolymers such as Poloxamer 188 with an HLB of 29 (col. 10, lin. 40-45, col. 16, lin. 15-45). The particles are included into pharmaceutical formulation comprising carriers and excipients (claim 19). Regarding the stability of the particles, it is the position of the Examiner that such limitations are functional and dependent from the compositional components of the particles. Since a composition and its properties cannot be separated, the same components must have the same properties. As such the prior art discloses amphiphillic particles comprising the same

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amphiphillic polymers and incorporated active agents, therefor their stability must also be the same.

Regarding claim 10, it is the position of the Examiner that the claim limitations reciting the incubation time and temperature are merely product by process limitation and do not overcome the prior art. The claim recites particles comprising an active agent incorporated into a particle comprising amphiphillic polymers. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

For these reasons the claims are anticipated.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 8:00-5:30; every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618